NAUSICAA
MEDICAL

EU DECLARATION OF CONFORMITY

MANUFACTURER:

Corporate Name : NAUSICAA MEDICAL
Single registration number (SRN) : FR-MF-000000955
Head Office adress : ZA Pôle Actif-30660 GALLARGUES LE MONTUEUX-FRANCE

NAUSICAA MEDICAL:

- certify that the UE declaration of conformity is issued under the sole of our responsability as manufacturer
- confirms that the following devices are in conformity with the Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices

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DEVICE:

Basic UDI-DI : 37014294NAUSIFLOWAUTOQGN
Product and trade name : NAUSIFLOW 100 AUTO QUATTRO SYSTEM
Model : NAUSIFLOW 100 AUTO QUATTRO (PUMP) ; NAUSIFLOW 100-512 (MATRESS) ; NAUSIFLOW 100-834 (MATRESS)
Products codes : NA100QTO-COMP-PM ; NA512-MAT85-PM ; NA834-MAT85-PM

Intended purpose : pressure ulcer prevention. Alleviation of an injury (pressure care systems)

Risk class of the device (Annexe VIII) : Class I

Harmonised standards used and in relation to which conformity is declared :

EN 60601-1 :2006/A1 : 2013 Medical electrical equipment - Part 1 : General requirements for basic safety and essential performance
EN 60601-1-2 : 2015 Medical electrical equipment - Part 1-2 : General requirements for basic safety and essential performance - Collateral Standard : Electromagnetic disturbances – Requirements and tests
EN 60601-1-11 :2010 Medical electrical equipment - Part 1-11 : General requirements for basic safety and essential performance - Collateral standard : Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN ISO 14971 : 2019 Medical devices - Application of risk management to medical devices
EN ISO 15223-1 : 2021 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1 : General requirements

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Place and date of the declaration

Gallargues le Montueux, 7th June 2022

Bruce ANDURAND
President